

Notice on Implementation of Office for Human Research Protections (OHRP) Guidance on Research Involving Coded Private Information and Biological Specimens

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Key Dates

Release Date: September 17, 2004

Issued by

National Institutes of Health (NIH), (<http://www.nih.gov/>)

On August 10, 2004, OHRP issued Guidance on Research Involving Coded Private Information of Biological Specimens, which is available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>. This guidance is addressed to Institutional Review Boards (IRBs), Investigators, and funding agencies. This guidance will affect the way the NIH and the applicant institutions process applications involving coded private information and biological specimens from human donors. At this point, the National Institutes of Health (NIH) is assessing how best to implement the OHRP Guidance while taking into consideration the requirements defined in Title 45 CFR Part 46 (Protection of Human Subjects) for funding agencies (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.120>). We are also trying to assess the impact of this policy change on the NIH clinical research portfolio. In order to minimize confusion for applicants considering projects involving coded private information and biological specimens, the NIH will require grant applications and contract proposals to adhere to existing procedures described in the PHS 398 and in applicable Requests for Proposals (RFPs) until new instructions are announced. Additionally, reviewers will continue to use existing instructions in evaluating these applications and proposals.

The NIH will develop appropriate instructions related to this guidance with the expectation that implementation will occur with the January 10, 2005 receipt date. In preparation for implementation, all appropriate forms and announcements will be modified and training for reviewers will be provided.

To reiterate, the Guidance announced on August 10 by OHRP regarding coded private information and biological specimens will not be implemented by the NIH prior to the January 10 receipt date. If you have questions about the OHRP Guidance, please contact OHRP by email at ohrp@osophs.dhhs.gov.

If you have questions about the NIH plans for implementation, please contact the Office of Extramural Programs, Office of Extramural Research, Office of the Director, NIH by email at OEPMailbox@mail.nih.gov.

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